UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

# NOTICE OF ALLOWANCE AND FEE(S) DUE

50163

WANG & HO 66 HILLTOP ROAD

MILLINGTON, NJ 07946

7590

09/18/2009

EXAMINER

SCHLIENTZ, NATHAN W

PAPER NUMBER

1616

DATE MAILED: 09/18/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/558,151	11/25/2005	Yuwan Wang	P050002US	1882

TITLE OF INVENTION: DIMETHICONE-CONTAINING SUSTAINED RELEASE INJECTION FORMULATION

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	12/18/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

#### PART B - FEE(S) TRANSMITTAL

## Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or <u>Fax</u> (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where

appropriate. All further indicated unless correcte maintenance fee notificat	correspondence includired below or directed oth tions.	ng the Patent, advance on nerwise in Block 1, by (a	ders and notification of rand) specifying a new corres	maintenance fees waspondence address;	rill be and/or	mailed to the current (b) indicating a sepa	correspondence address as rate "FEE ADDRESS" for
CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)				(s) Transmittal. Thi ers. Each additional	s certif I paper	icate cannot be used for	r domestic mailings of the or any other accompanying nt or formal drawing, must
WANG & HO 66 HILLTOP RO MILLINGTON,		/2009	I he Stat addi tran	Cerreby certify that the es Postal Service we ressed to the Mail smitted to the USP.	t <b>ificate</b> is Fee(s ith suf Stop ΓΟ (57	of Mailing or Transı s) Transmittal is being ficient postage for firs ISSUE FEE address 1) 273-2885, on the da	nission deposited with the United t class mail in an envelope above, or being facsimile ate indicated below.
							(Depositor's name)
							(Signature)
							(Date)
APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR		ATTO	RNEY DOCKET NO.	CONFIRMATION NO.
10/558,151 FITLE OF INVENTION	11/25/2005 : DIMETHICONE-CON	TAINING SUSTAINED	Yuwan Wang DRELEASE INJECTION I	FORMULATION		P050002US	1882
APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE	E FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0		\$1055	12/18/2009
EXAM	INER	ART UNIT	CLASS-SUBCLASS	]			
SCHLIENTZ,	NATHAN W	1616	424-405000	J			
"Fee Address" indi PTO/SB/47; Rev 03-0 Number is required.  3. ASSIGNEE NAME A	ND RESIDENCE DATA less an assignee is ident h in 37 CFR 3.11. Comp	" Indication form aed. Use of a Customer A TO BE PRINTED ON T	(1) the names of up to or agents OR, alternative (2) the name of a single registered attorney or a 2 registered patent attoolisted, no name will be THE PATENT (print or type data will appear on the part of the	vely, e firm (having as a agent) and the name rneys or agents. If a printed.  De) atent. If an assigne assignment.	membes of upono name	er a 2p to see is 3	ocument has been filed for
			<u>-</u>				up entity Government
4a. The following fee(s) are submitted:  ☐ Issue Fee ☐ Publication Fee (No small entity discount permitted) ☐ Advance Order - # of Copies			4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)  A check is enclosed.  Payment by credit card. Form PTO-2038 is attached.  The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number (enclose an extra copy of this form).				
a. Applicant claims	<b>tus</b> (from status indicated s SMALL ENTITY statu	ıs. See 37 CFR 1.27.	☐ b. Applicant is no long				
NOTE: The Issue Fee and interest as shown by the r	d Publication Fee (if requeecords of the United Sta	uired) will not be accepted tes Patent and Trademark	d from anyone other than to Office.	he applicant; a regi	stered a	attorney or agent; or th	e assignee or other party in
Authorized Signature				Date			
Typed or printed name				o .			
This collection of inform an application. Confident submitting the completed this form and/or suggesti Box 1450. Alexandria, V	ation is required by 37 C tiality is governed by 35 I application form to the ions for reducing this but irginia 22313-1450 Dec	FR 1.311. The informatic U.S.C. 122 and 37 CFR USPTO. Time will vary rden, should be sent to the	on is required to obtain or r 1.14. This collection is est depending upon the indiv e Chief Information Office COMPLETED FORMS TO	retain a benefit by the timated to take 12 revidual case. Any coer, U.S. Patent and THIS ADDRESS	ne publ ninutes mment Traden	ic which is to file (and to complete, includin s on the amount of tir nark Office, U.S. Depa D.TO: Commissioner	by the USPTO to process) g gathering, preparing, and ne you require to complete urtment of Commerce, P.O. for Patents P.O. Box 1450.

Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450

P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/558,151	11/25/2005	Yuwan Wang	P050002US	1882	
50163 75	590 09/18/2009		EXAMINER		
WANG & HO			SCHLIENTZ,	NATHAN W	
66 HILLTOP ROA	<del></del>		ART UNIT	PAPER NUMBER	
MILLINGTON, N	J 07946		1616		
			DATE MAILED: 09/18/200	9	

# Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 346 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 346 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

	Application No.	Applicant(s)	
	10/558,151	WANG ET AL.	
Notice of Allowability	Examiner	Art Unit	
	Nathan W. Schlientz	1616	
The MAILING DATE of this communication apperall claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIOF of the Office or upon petition by the applicant. See 37 CFR 1.313 1.   This communication is responsive to Response filed 25 Au	(OR REMAINS) CLOSED in to or other appropriate commun GHTS. This application is sure and MPEP 1308.	his application. If not included ication will be mailed in due co	urse. <b>THIS</b>
2. $\square$ The allowed claim(s) is/are 22 and 23.			
<ul> <li>3.  Acknowledgment is made of a claim for foreign priority una)  All b)  Some* c)  None of the: <ol> <li>Certified copies of the priority documents have</li> <li>Certified copies of the priority documents have</li> <li>Copies of the certified copies of the priority documents have</li> <li>Copies of the certified copies of the priority documents have</li> <li>Ropies of the certified copies of the priority documents have</li> <li>Fertified copies not received:</li> </ol> </li> <li>Applicant has THREE MONTHS FROM THE "MAILING DATE" on the delow. Failure to timely comply will result in ABANDONM THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.</li> <li>A SUBSTITUTE OATH OR DECLARATION must be submitted.</li> </ul>	e been received.  been received in Application cuments have been received of this communication to file a lENT of this application.	No  n this national stage application reply complying with the requi	rements
INFORMAL PATENT APPLICATION (PTO-152) which give  5. CORRECTED DRAWINGS ( as "replacement sheets") mus  (a) including changes required by the Notice of Draftspers  1) hereto or 2) to Paper No./Mail Date  (b) including changes required by the attached Examiner's Paper No./Mail Date  Paper No./Mail Date  Identifying indicia such as the application number (see 37 CFR 1. each sheet. Replacement sheet(s) should be labeled as such in the depose attached Examiner's comment regarding REQUIREMENT I	st be submitted. Son's Patent Drawing Review Son Amendment / Comment or in Son Amendment / Comme	(PTO-948) attached  the Office action of  drawings in the front (not the ba 1.121(d).  RIAL must be submitted. Not	-
Attachment(s)  1. ☐ Notice of References Cited (PTO-892)  2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)  3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date  4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material	6.	rmal Patent Application nmary (PTO-413), ail Date mendment/Comment tatement of Reasons for Allowa	ance

# **NOTICE OF ALLOWANCE**

Claims 22 and 23 (renumbered as claims 1 and 2, respectively) are allowed.

### Reasons for Allowance

The following is an examiner's statement of reasons for allowance: Applicants claims are drawn to a sustained release injection formulation comprising an avermectin, hydrogenated castor oil, local analgesic, antioxidant (BHT, BHA, and/or propyl gallate), and dimethicone. Applicant's specification states on pg. 2, In. 8-11, "The drugs and suspension agents (e.g. hydrogenated castor oil) described in the present invention are substantially insoluble and do not swell in dimethicone. These features are an important basis for dimethicone to be used to prepare the injection formulation of the present invention." EP 0 535 734 A1 (Chen et al.) teaches long acting injection formulations comprising avermectins, hydrogenated castor oil, antioxidants (BHT, BHA, and/or propyl gallate), and a hydrophobic non-aqueous vehicle. However, Chen et al. do not teach dimethicone as the hydrophobic non-aqueous vehicle and specifically states, "Any physiologically and pharmaceutically acceptable injection solvent (i.e., hydrophobic nonaqueous vehicle) may be used so long as the avermectin compound is soluble therein." Therefore, the Chen et al. teaches away from the use of dimethicone in which the avermectin and hydrogenated castor oil are substantially insoluble and do not swell.

Application/Control Number: 10/558,151 Page 3

Art Unit: 1616

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### **Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**NWS** 

/Johann R. Richter/ Supervisory Patent Examiner, Art Unit 1616